

# **EPA Reg. No. 74054-7**

# Material Sent for Data Extraction

Reg. # 74054-7

Description: new Production

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated 2/27/14

☐ Notification Dated \_\_\_\_\_

☐ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

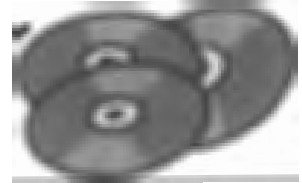
File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: S Hill

Phone: 347-8961 Division: RD

Date: 3/6/14

**NEW APPLICATIONS**



**DATE:** APR 15 2013

**FILE REG NUMBER:** 74054-T

**FEP (OPPIN ENTRY)** LV APR 16 2013

**(Initial & Date)**

**FILE ROOM:** \_\_\_\_\_

**(Initial & Date)**

**SIG:** \_\_\_\_\_

**(Initial & Date)**

**FILE ROOM:** \_\_\_\_\_

**(Initial & Date)**

**ASSIGN TO PM: AD** ✓ **RD** 20 **BPPD** \_\_\_\_\_

**\_\_\_\_\_ JACKET TO SHELF (DATA)**



# U.S. ENVIRONMENTAL PROTECTION

Office of Chemical Safety and Pollution Prevention  
Office of Pesticide Programs  
Registration Division (7504P)  
1200 Pennsylvania Ave., N.W.  
Washington, DC 20460

## NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

EPA Reg. Number:

74054-7

Date of Issuance:

FEB 27 2014

Term of Issuance:

Unconditional

Name of Pesticide Product:

Azoxystrobin Technical NC

Name and Address of Registrant (include ZIP Code):

Irvita Plant Protection N.V.  
4515 Falls of Neuse Rd. Suite 300  
Raleigh, NC 27609

Mailed to Agent:

Bert Volger  
MANA  
3120 Highwoods Blvd. Suite 100  
Raleigh, NC 27604

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA sec. 4.

Page 1 of 2

Signature of Approving Official:

Shaja B. Joyner, Product Manager 20  
Fungicide Branch/Registration Division/OPP/OCSPP (7505P)

Date:

2/27/14

2. Change the product registration number on the label to EPA Reg. No. 74054-7.
3. Submit one copy of the revised final printed label for the record before the product is released for shipment.

If these requirements are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A copy of your label stamped "Accepted with Comments" is enclosed for your records.

The basic CSF submitted 6/28/13 is acceptable and will be added to the regulatory file for the product. If you have any questions or comments regarding this letter, please contact Shaunta Hill at (703) 347-8961 or via e-mail at [hill.shaunta@epa.gov](mailto:hill.shaunta@epa.gov).



Shaja Joyner  
Product Manager 20  
Fungicide Branch  
Registration Division (7505P)

Enclosure:

Label stamped "Accepted with Comments".  
Product Chemistry review dated 2/18/14.  
Acute Toxicity review dated 2/18/14.

# AZOXYSTROBIN TECHNICAL NC

FUNGICIDE FOR MANUFACTURING USE ONLY

## ACTIVE INGREDIENT:

% BY WT

Azoxystrobin: methyl(E)-2-(2-[6-(2-cyanophenoxy)pyrimidin-4-yloxyphenyl]-3-methoxyacrylate\* .....

98.8%

OTHER INGREDIENTS: ..... 1.2%

**TOTAL** 100.0%

\*IUPAC

KEEP OUT OF REACH OF CHILDREN

## CAUTION

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:

FEB 27 2014

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act, c/o  
as amended, for the pesticide  
registered under EPA Reg. No.

74054-1

## Manufactured for:

Irvita Plant Protection N.V.

Makhteshim Agan of North America, Inc.

3120 Highwoods Blvd., Suite 100

Raleigh, NC 27604

EPA Reg. No. 74054-xx

EPA Est. No. XXXXXXXXXX

NET CONTENTS: \_\_\_\_\_ Pounds (Kilos)

## FIRST AID

<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15 to 20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>IF INHALED:</b>	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance; then give artificial respiration, preferably mouth-to-mouth if possible.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"><li>• Call a poison control center or doctor immediately for treatment advice.</li><li>• Have a person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give anything to an unconscious person.</li></ul>
<b>If on eyes:</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes; then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>Have the product container or label with you when calling a poison control center or doctor or going for treatment.</b>	

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION.** Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

The active ingredient, azoxystrobin, in this product can be persistent for several months or longer. Azoxystrobin has degradation products which have properties similar to chemicals which are known to leach through soil to groundwater under certain conditions as a result of labeled use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

This pesticide is toxic to freshwater and estuarine/marine fish and aquatic invertebrates. Keep out of lakes, streams, ponds, tidal marshes, or estuaries. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Notify state and/or federal authorities immediately if you observe any adverse environmental effects due to the use of this product.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product which may be labeled for use patterns as listed on this label.

**For Manufacturing Use Only into a Fungicide for the Following Uses:**

1. Terrestrial Nonfood: Uses on golf courses, lawns, and landscape areas around residential, institutional, public, commercial, and industrial buildings, parks, recreational areas, and athletic fields; uses on ornamentals grown in container, bench, flat, plug, bed, or in the field, in greenhouses, shade houses, outdoor nurseries, retail nurseries, and other landscape areas; and
2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
3. Uses for experimental purposes that are in compliance with USEPA requirements.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Shaunta Hill at [hill.shaunta@epa.gov](mailto:hill.shaunta@epa.gov) or 703-347-8961 or myself at [joyner.shaja@epa.gov](mailto:joyner.shaja@epa.gov) or 703-308-3194.

Sincerely,

A handwritten signature in black ink, appearing to read "Shaja B. Joyner". The signature is fluid and cursive, with the first name "Shaja" being the most prominent part.

Shaja B. Joyner  
Product Manager 20  
Fungicide Branch  
Registration Division (7504P)

Attachments: EPA label comments



**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION.** Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

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2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
3. Uses for experimental purposes that are in compliance with USEPA requirements.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, cover spill with moist sand, soil, or sawdust. Transfer to a container for disposal. Wash the spillage area with water. Washings must be prevented from entering surface water drains.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

**CONTAINER HANDLING: Nonrefillable Container (flexible-bag-all weights):** Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

### LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Ivita Plant Protection, N.V.. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, Ivita Plant Protection, N.V. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Ivita Plant Protection, N.V. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Ivita Plant Protection, N.V. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Ivita Plant Protection, N.V.'s election, the replacement of product.

## Hill, Shaunta

---

**From:** Bert Volger [bertvolger@ceresinternational.com]  
**Sent:** Tuesday, February 25, 2014 9:06 AM  
**To:** Hill, Shaunta  
**Cc:** Joyner, Shaja  
**Subject:** Azoxystrobin Tech  
**Attachments:** 053883-00xxx-20140225b Azoxystrobin Technical NC-Master label -EPA comments incorp.-subm 2-25-2014.pdf

Hi Shaunta,

Attached you will find the revised label with your label comments incorporated.

Please let me know if you have any further comments.

S# 948434

Thanks,  
Bert

---

**From:** Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]  
**Sent:** Thursday, February 20, 2014 4:02 PM  
**To:** Bert Volger  
**Cc:** Joyner, Shaja  
**Subject:** FW:

Bert Volger  
Irvita Plant Protection N.V.  
c/o Makhteshim Agan of North America, Inc.  
3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

Hello Bert,

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified on the attached label.

Please review and respond to the attached letter as soon as possible. If you have any questions, please feel free to contact either myself or Shaja Joyner (joyner.shaja@epa.gov or 703-308-3194).

Regards,

\*\*\*\*\*

Shaunta Hill, Ph. D  
U.S. EPA :Office of Chemical Safety and Pollution Prevention  
Registration Division/Fungicide Branch  
1200 Pennsylvania Avenue, NW (7504P)  
Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920  
E-mail: [hill.shaunta@epa.gov](mailto:hill.shaunta@epa.gov)

# AZOXYSTROBIN TECHNICAL NC

FUNGICIDE FOR MANUFACTURING USE ONLY

**ACTIVE INGREDIENT:****% BY WT**

Azoxystrobin: methyl(E)-2-(2-[6-(2-cyanophenoxy)pyrimidin-4-yloxyphenyl]-3-methoxyacrylate\* .....

98.8%

**OTHER INGREDIENTS:** .....

1.2%

**TOTAL** 100.0%

\*IUPAC

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

**Manufactured for:**

Ivita Plant Protection N.V.

c/o Makhteshim Agan of North America, Inc.

3120 Highwoods Blvd., Suite 100

Raleigh, NC 27604

SH 948434  
ELL # 015102

EPA Reg. No. 74054-xx

EPA Est. No. XXXXXXXXXX

NET CONTENTS: \_\_\_\_\_ Pounds (Kilos)

### FIRST AID

**IF ON SKIN OR CLOTHING:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15 to 20 minutes.
- Call a poison control center or doctor for treatment advice.

**IF INHALED:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance; then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:**

- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.

**If on eyes:**

- Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.
- Remove contact lenses, if present, after the first 5 minutes; then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

**Have the product container or label with you when calling a poison control center or doctor or going for treatment.**

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION.** Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

The active ingredient, azoxystrobin, in this product can be persistent for several months or longer. Azoxystrobin has degradation products which have properties similar to chemicals which are known to leach through soil to groundwater under certain conditions as a result of labeled use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

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Notify state and/or federal authorities immediately if you observe any adverse environmental effects due to the use of this product.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product which may be labeled for use patterns as listed on this label.

**For Manufacturing Use Only into a Fungicide for the Following Uses:**

1. Terrestrial Nonfood: Uses on golf courses, lawns, and landscape areas around residential, institutional, public, commercial, and industrial buildings, parks, recreational areas, and athletic fields; uses on ornamentals grown in container, bench, flat, plug, bed, or in the field, in greenhouses, shade houses, outdoor nurseries, retail nurseries, and other landscape areas; and
2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
3. Uses for experimental purposes that are in compliance with USEPA requirements.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, cover spill with moist sand, soil, or sawdust. Transfer to a container for disposal. Wash the spillage area with water. Washings must be prevented from entering surface water drains.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

**CONTAINER HANDLING: Nonrefillable Container (flexible-bag-all weights):** Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

### LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Irvita Plant Protection, N.V.. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, Irvita Plant Protection, N.V. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Irvita Plant Protection, N.V. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Irvita Plant Protection, N.V. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Irvita Plant Protection, N.V.'s election, the replacement of product.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**FEB 20 2014**

Bert Volger  
Irvita Plant Protection N.V.  
c/o Makhteshim Agan of North America, Inc.  
3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

Dear Mr. Volger,

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified on the attached label.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

- (a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
- (b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
- (c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

(Continued on page 2)

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Shaunta Hill at [hill.shaunta@epa.gov](mailto:hill.shaunta@epa.gov) or 703-347-8961 or myself at [joyner.shaja@epa.gov](mailto:joyner.shaja@epa.gov) or 703-308-3194.

Sincerely,

A handwritten signature in black ink, reading "Shaja B. Joyner". The signature is fluid and cursive, with the first name "Shaja" being the most prominent part.

Shaja B. Joyner  
Product Manager 20  
Fungicide Branch  
Registration Division (7504P)

Attachments: EPA label comments



# AZOXYSTROBIN TECHNICAL NC

FUNGICIDE FOR MANUFACTURING USE ONLY

**ACTIVE INGREDIENT:** Azoxystrobin: methyl(E)-2-(2-[6-(2-cyanophenoxy)pyrimidin-4-yloxyphenyl]-3-methoxyacrylate\* ..... 98.8%  
**OTHER INGREDIENTS:** ..... 1.2%  
**TOTAL** 100.0%

\*IUPAC


**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**Manufactured for:**  
 Irvita Plant Protection N.V.  
 c/o Makhteshim Agan of North America, Inc.  
 3120 Highwoods Blvd., Suite 100  
 Raleigh, NC 27604

EPA Reg. No. 74054-xx

EPA Est. No. [REDACTED]

NET CONTENTS: \_\_\_\_\_ Pounds (Kilos)

FIRST AID 	
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15 to 20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance; then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	

## Summary of Comments on 2-day letter label cmts 2\_20\_14.pdf

Page: 1

Number: 1 Author: S. Hill Subject: Socky Note Date: 2/18/2014 3:20:57 PM  
 According to your cover letter dated April 10, 2013 this product is in toxicity category IV by the oral exposure route and category III for eye irritation. The oral study in MRID 49102604 indicates an LD50 >2000 mg/kg (category IV requires an LD50 >5000 mg/kg, and the eye study in MRID 49102607 indicates this formulation is in category IV (not III) for eye irritation.  
 Per these findings, the following changes are required.  
 1. Revise the First Aid statements to reflect the following order and text. If you wish to retain the "If In Eyes" text as presented, it must appear after "If Swallowed".  
 If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. If inhaled: Move the person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, cover spill with moist sand, soil, or sawdust. Transfer to a container for disposal. Wash the spillage area with water. Washings must be prevented from entering surface water drains.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

**CONTAINER HANDLING:** Nonrefillable Container (flexible-bag-all weights): Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

#### LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Irvita Plant Protection, N.V.. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, Irvita Plant Protection, N.V. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Irvita Plant Protection, N.V. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Irvita Plant Protection, N.V. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Irvita Plant Protection N.V.'s election, the replacement of product.

Mester Intl. Acropetroleum Technical Inc. - authorized 7-2-2013

#### PRECAUTIONARY STATEMENTS

##### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION.** Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

##### ENVIRONMENTAL HAZARDS

The active ingredient, azoxystrobin, in this product can be persistent for several months or longer. Azoxystrobin has degradation products which have properties similar to chemicals which are known to leach through soil to groundwater under certain conditions as a result of labeled use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

This pesticide is toxic to freshwater and estuarine/marine fish and aquatic invertebrates. Keep out of lakes, streams, ponds, tidal marshes, or estuaries. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Notify state and/or federal authorities immediately if you observe any adverse environmental effects due to the use of this product.

##### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product which may be labeled for use patterns as listed on this label.

For Manufacturing Use Only Into a Fungicide for the Following Uses:

1. Terrestrial Nonfood: Uses on golf courses, lawns, and landscape areas around residential, institutional, public, commercial, and industrial buildings, parks, recreational areas, and athletic fields; uses on ornamentals grown in container, bench, flat, plug, bed, or in the field, in greenhouses, shade houses, outdoor nurseries, retail nurseries, and other landscape areas; and
2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
3. Uses for experimental purposes that are in compliance with USEPA requirements.

Revised page 2 to correct MRID # for GLN study 830.1550.

D414362 + 411747

74054-T

BARCODE: D414362 & 411747; Reg No.: 74054-T; PRODUCT: Azoxystrobin Technical

**SUMMARY OF FINDINGS:**

Table 1. Manufacturing and Impurity Data for Fomesafen Technical				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	499676-01	A	
830.1600	Description of materials used to produce the product	499676-01	A	
830.1620	Description of production process	499676-01	A	
830.1670	Discussion of formation of impurities	499676-01	A	
830.1700	Preliminary analysis	491026-02	A	The NC of AI (98.8%) is supported by an analysis of 5 batches. Analysis agrees with the label claim NC.
830.1750	Certified limits	499676-01	A	
830.1800	Enforcement analytical method	499676-01	A	Validated GC-MS with FID detector for quantification.
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)				

**830 Series Subgroup B (Physical-Chemical Properties)**

Table 2: Physical and Chemical Properties of Fomesafen Technical				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	491026-03	A	Yellow
830.6303	Physical state	491026-03	A	Crystalline solid
830.6304	Odor	491026-03	A	Odorless
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	491026-03	A	Study at 54 C for two weeks indicated no degradation, discoloration or other physical changes
830.6314	Oxidation/reduction: chemical incompatibility	491026-03	A	Azoxystrobin TGA1 was found to be non-reactive towards iron powder, water, NH4I-12P04, KMnO4 an kerosene.
830.6315	Flammability		A.	Product is not flammable.
830.6316	Explosibility		A.	Product does not contain explosive components
830.6317	Storage stability		G	No data submitted
830.6319	Miscibility		N.A.	Product is not an EC nor mixed with petroleum solvents
830.6320	Corrosion characteristics		G	No data submitted
830.7000	pH	491026-03	A	6.66 (1% w/w dilution in DI water)
830.7050	UV/Visible absorption	491026-03	A	pH 6.281
				log ε (197 nm)= 4.85
				pH 0.654
				log ε (204 nm)= 4.73
				pH 13.213
				log ε (220, 273 nm)= 4.48, 4.02



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**BARCODE:** D414362 & 411747; **Reg No.:** 74054-T; **PRODUCT:** Azoxystrobin Technical

**DATE:** February 18, 2014

**FROM:** Akiva Abramovitch, Ph.D.  
Technical Review Branch / RD (7505P)

**THROUGH:** Shyam B. Mathur, Ph.D.  
Product Chemistry Team Leader  
Technical Review Branch/RD (7505P)

SBW 02119114

**TO:** Shaunta Hill/William Cutchin, Product Manager, RM 20  
Fungicide Branch / RD (7505P)

**SUBJECT:** Product Chemistry Review of Azoxystrobin Technical

**DECISION NO.:** 477664

**PC CODE:** 128810

**REGISTRANT:** Irvita Plant Protection

**USE:** Technical Fungicide

**FOOD USE:** Yes ☒ No ☐

**MRID NUMBERS:** 499676-01 and 491026-01 through -03

**INTRODUCTION:**

The registrant is seeking the registration of a new manufacturing use product of Azoxystrobin Technical. This product will be produced at [REDACTED]. The active ingredient in this product is Azoxystrobin at a label nominal concentration of 98.8% a.i and an identical label claim. This product is intended for use in the manufacture of fungicide end-use products. In support of this petition, the registrant has submitted a draft label and product chemistry data contained in MRID# 499676-01 and 491026-01 through -03 and a revised basic CSF dated June 28, 2013 (original CSF dated April 10, 2013 revised per screen comments in DP 411898)

\*Commercial/financial information may be entitled to confidential treatment\*

BARCODE: D414362 & 411747; Reg No.: 74054-T; PRODUCT: Azoxystrobin Technical

SUMMARY OF FINDINGS:

*wrong MRID # listed*

Table 1. Manufacturing and Impurity Data for Fomesafen Technical				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	491676-01	A	
830.1600	Description of materials used to produce the product	491676-01	A	
830.1620	Description of production process	491676-01	A	
830.1670	Discussion of formation of impurities	491676-01	A	
830.1700	Preliminary analysis	491026-02	A	The NC of AI (98.8%) is supported by an analysis of 5 batches. Analysis agrees with the label claim NC.
830.1750	Certified limits	491676-01	A	
830.1800	Enforcement analytical method	491676-01	A	Validated GC-MS with FID detector for quantification.
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)				

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of Fomesafen Technical										
GLN	Requirement	MRID	Status	Result or Deficiency						
830.6302	Color	491026-03	A	Yellow						
830.6303	Physical state	491026-03	A	Crystalline solid						
830.6304	Odor	491026-03	A	Odorless						
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	491026-03	A	Study at 54 C for two weeks indicated no degradation, discoloration or other physical changes						
830.6314	Oxidation/reduction: chemical incompatibility	491026-03	A	Azoxystrobin TGA1 was found to be non-reactive towards iron powder, water, NH4I-12P04, KMnO4 an kerosene.						
830.6315	Flammability		A.	Product is not flammable.						
830.6316	Explosability		A.	Product does not contain explosive components						
830.6317	Storage stability		G	No data submitted						
830.6319	Miscibility		N.A.	Product is not an EC nor mixed with petroleum solvents						
830.6320	Corrosion characteristics		G	No data submitted						
830.7000	pH	491026-03	A	6.66 (1% w/w dilution in DI water)						
830.7050	UV/Visible absorption	491026-03	A	<table><tr><td>pH 6.281</td><td>log e (197 nm)= 4.85</td></tr><tr><td>pH 6.654</td><td>log e (204 nm)= 4.73</td></tr><tr><td>pH 13.213</td><td>log e (220, 273 nm)= 4.46, 4.02</td></tr></table>	pH 6.281	log e (197 nm)= 4.85	pH 6.654	log e (204 nm)= 4.73	pH 13.213	log e (220, 273 nm)= 4.46, 4.02
pH 6.281	log e (197 nm)= 4.85									
pH 6.654	log e (204 nm)= 4.73									
pH 13.213	log e (220, 273 nm)= 4.46, 4.02									

**BARCODE:D414362 &411747; Reg No.: 74054-T; PRODUCT: Azoxystrobin Technical**

Table 2: Physical and Chemical Properties of Fomesafen Technical

GLN	Requirement	MRID	Status	Result or Deficiency
830.7100	Viscosity		W	Solid./ waiver
830.7200	Melting point	491026-03	A.	116.3 C
830.7220	Boiling point		NA	Solid , waiver
830.7300	Density	491026-03	A	1.243 gm/ml @ 20 °C
830.7370	Dissociation constants in water		A	No dissociation
830.7550	Partition coefficient	491026-03	A	Log P o/w=2.42
830.7840	Water solubility:	491026-03	A	8.4 mg/L at 20 C at pH 7.3 at 18 C
830.7950	Vapor pressure	491897-03	A	$2.4 \times 10^{-3}$ m Pa

Y = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)

**CONCLUSIONS:**

TRB has reviewed this submission and reports the following findings:

1. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.330, 158.340, 158.345, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of production process, discussion of formation of impurities, preliminary analysis, certified limits, and enforcement analytical method.
2. The five batch analysis supports the composition shown on the CSF for basic formulation. The mean purity of Azoxystrobin Technical NC was measured at 98.8% w/w with a range from 98.6 to 99.1% w/w, which is in support of the label claim and nominal concentration of 98.8% . The lower and upper limits can range from 95.8 to 98.7% w/w. This range in concentration . The total content for all [REDACTED] impurities associated with the active ingredient ranges between [REDACTED] and [REDACTED] resulting in a good overall closure of 98.8 to 99.3% w/w (mean of 98.8% w/w).
3. The registrant declared unidentified impurities at <0.1% to be of no of toxicological concern. All identified impurities have upper certified limit but are on no toxicological concerns.
4. This submission satisfies the remaining data requirements as specified in 40 CFR 158.310 with respect to physical and chemical properties.
5. The product chemistry data requirements have been satisfied with the exception of the storage stability and corrosion characteristics data.
6. The basic CSF dated June 28, 2013 for [REDACTED] is acceptable.

**BARCODE:**D414362 &411747; **Reg No.:** 74054-T; **PRODUCT:** Azoxystrobin Technical

\*Pages 24-25 Manufacturing process information may be entitled to confidential treatment\*





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

February 18, 2014

**MEMORANDUM: ACUTE TOXICITY DERS FOR 74054-T**

Subject: Name of Pesticide Product: AZOXYSTROBIN TECHNICAL NC  
EPA Reg. No. /File Symbol: 74054-T  
DP Barcode: DP 411748  
Decision No.: 477664  
Action Code: R333  
Submission: #933747  
E-Sub: -  
PC Code: 128810 (Azoxystrobin: 96%)

From: Byron T. Backus, Ph.D., Toxicologist  
Technical Review Branch  
Registration Division (7505P)

*Byron T. Backus*  
*Feb-18-2014*

*Haslin*  
*Team Leader - Tox*

To: Shaunta Hill RM 20  
Fungicide Branch  
Registration Division (7505P)

Registrant: IRVITA PLANT PROTECTION N.V.

**FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	by wt.
128810 Azoxystrobin	96.0%
<u>Other Ingredients:</u>	4.0%
TOTAL	100.0%

**ACTION REQUESTED:** "...Please provide an analysis/determination of acceptability for the attached acute tox data by the listed LSDD... Copies of the incoming letter, CSF, transmittal form and data matrix are attached for your reference/review..."

**BACKGROUND:** The material received by TRB includes 6 acute toxicity studies (MRIDs 49102604 through 49102609), a proposed label (with the signal word CAUTION), a CSF dated April 10, 2013, and a cover letter dated April 10, 2013.

## COMMENTS AND RECOMMENDATIONS:

1. The six acute toxicity studies have all been classified as acceptable and can be used to satisfy the acute toxicity data requirements for EPA File Symbol 74054-T, which then has the following acute toxicity profile:

Acute Oral LD <sub>50</sub>	III*	Acceptable	MRID 49102604
Acute Dermal LD <sub>50</sub>	III	Acceptable	MRID 49102605
Acute Inhalation LC <sub>50</sub>	III	Acceptable	MRID 49102606
Primary Eye Irritation	IV*	Acceptable	MRID 49102607
Primary Dermal Irritation	IV	Acceptable	MRID 49102608
Dermal Sensitization	Negative	Acceptable	MRID 49102609

\*According to the registrant's cover letter dated April 10, 2013 this product is in toxicity category IV by the oral exposure route and category III for eye irritation. The oral study in MRID 49102604 indicates an LD<sub>50</sub> >2000 mg/kg (category IV requires an LD<sub>50</sub> >5000 mg/kg, and the eye study in MRID 49102607 indicates this formulation is in category IV (not III) for eye irritation.

2. Based on the acute toxicity profile given above, the following is the precautionary and first aid labeling for 74054-T, as obtained from the Label Review System:

**PRODUCT ID #:** 074054-00007

**PRODUCT NAME:** AZOXYSTROBIN TECHNICAL NC

### PRECAUTIONARY STATEMENTS

**SIGNAL WORD:** CAUTION

#### Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if inhaled. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse.

#### First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

3. The CSF (dated April 10, 2013) for 74054-T should also be reviewed and accepted by the TRB Chemistry Team.

**Reviewer: Byron T. Backus, Ph.D.**  
**Risk Manager (EPA): 20**

**Date:** February 18, 2014

The following table is the Acute Toxicity Data Evaluation Record (DER) for the acute toxicity studies for EPA File Symbol 74054-T:

<b>1. DP BARCODE:</b> 411748				
<b>2. PC CODE:</b> 128810				
<b>3. CURRENT DATE:</b> February 18, 2014				
<b>4. TEST MATERIAL:</b> Azoxystrobin TGAI (analytical purity 99.0%); Batch/Lot No. 20091005; described as a solid (yellow powder).				
<b>Study/Species/Lab Study # /Date</b>	<b>MRID</b>	<b>Results</b>	<b>Tox Cat</b>	<b>Core Grade</b>
Acute oral toxicity / rat / JAI Research Foundation Dept. of Toxicology, Gujarat India/ Lab Project ID 401-1-01-5259/ November 26, 2012 / OCSPP 870.1100; OECD 423	49102604	Oral LD50 > 2000 mg/kg (no deaths in 6 rats dosed at 2000 mg/kg). One group of 3 female Wistar rats was dosed with 2000 mg test material/kg (test material was suspended in vegetable oil and administered at a dose volume of 10 mL/kg). No mortalities were observed in these 3 rats and a second group of 3 female rats was then dosed at 2000 mg/kg. No mortality was observed in the second group. There were no signs of toxicity in either group. All rats gained weight from day 0 to 7 and again from day 7 to 14. No abnormalities were found at necropsy.	III	A
Acute dermal toxicity / rat / JAI Research Foundation Dept. of Toxicology, Gujarat India/ Lab Project ID 403-1-01-5260 / November 26, 2012 / OCSPP 870.1200; OECD 402	49102605	Dermal LD50 > 2000 mg/kg. Doses of 2000 mg/kg (each dose was moistened with 0.2 mL distilled water) were applied to 5M & 5F Wistar rats, with 24-hr dermal exposure. A control group of 5M & 5F rats was dosed with 0.2 mL distilled water. There were no signs of toxicity or mortality. All gained weight days 0-7 and 7-14. No abnormalities were found at necropsy.	III	A

Acute inhalation toxicity / rat / JAI Research Foundation Dept. of Toxicology, Gujarat India/ Lab Project ID 405-1-01-5261 / November 28, 2012 / OCSPP 870.1300; OECD 403	49102606	Inhalation LC50 > 0.565 mg/L. 3 Wistar rats/sex were exposed (head/nose only) for 4 hours to 0.565 mg/L (gravimetric concentration; nominal conc. = 11.765 mg/L). MMAD = 2.42 µm with a GSD = 2.61. 73.7% of the particles were less than or equal to 4.25 µm. There were no signs of toxicity and no deaths. All rats had slight weight losses (2 to 5 g) between day 0 and 1, but all gained weight day 0-7 and 7-14. No gross abnormalities were found at necropsy. Although only 3 rats/sex were exposed, study is acceptable because all survived (worst-case scenario if 2 additional rats/sex had been exposed would have been for them to die, but 3/5 per sex would still have survived).	III	A
Primary eye irritation / rabbit / JAI Research Foundation Dept. of Toxicology, Gujarat India/ Lab Project ID 407-1-01-5263 / November 30, 2012 / OCSPP 870.2400; OECD 405	49102607	100 mg was instilled into left eye of each of 3 rabbits. There was no corneal opacity and no iritis. Grade 1 conjunctival irritation was observed at 1 and 24 hrs in all 3 eyes, and in one eye at 48 hrs. One exposed eye had grade 1 chemosis at 24 hrs; all other scores were zero. All scores were clear (all scores zero) at 72 hrs.	IV	A
Primary dermal irritation / rabbit / JAI Research Foundation Dept. of Toxicology, Gujarat India/ Lab Project ID 406-1-01-5262 / December 4, 2012 / OCSPP 870.2500; OECD 404	49102608	500 mg azoxystrobin TGAI (moistened with 0.5 mL distilled water) was applied to a dermal site on each of 3 NZ white rabbits with 4-hr semiocluded exposure. All scores for edema were zero. for erythema were 1 at 1 hr and 1/3 scored 1 at 24 hrs. PDII = 0.33; all scores zero at 48 & 72 hrs.	IV	A

Dermal sensitization / guinea pig / JAI Research Foundation Dept. of Toxicology, Gujarat India/ Lab Project ID 408-1-01-5264 / December 3, 2012 / OCSPP 870.2600; OECD 406	49102609	Maximization Method: 10 Harley male guinea pigs received (Day 0) 3 pairs of 0.1 mL intradermal injections [#1: 1:1 v/v mixture of Freund's Complete Adjuvant (FCA) and distilled water; #2: 1.0% (w/v) azoxystrobin TGAI in propylene glycol; #3: 1.0% (w/v) azoxystrobin in propylene glycol and 1:1 mixture of FCA in distilled water]. Day 6: 10% w/v sodium lauryl sulphate in vaseline was applied on test area. Day 7: a patch with 100 mg azoxystrobin TGAI moistened with 0.2 mL 80% EtOH was applied to left flank and held in contact with occlusive dressing for 48 hrs. On Day 21 a patch with 100 mg azoxystrobin TGAI and 0.2 mL acetone was applied to right flank of 15 (5 control + 10 induced) guinea pigs. None of the 15 guinea pigs showed a positive response. Positive control study (with HCA) showed 8/20 (40%) positive response rate.	Not a sensitizer	A
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n.d. = not determined; Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap

# AZOXYSTROBIN TECHNICAL NC

FUNGICIDE FOR MANUFACTURING USE ONLY

## ACTIVE INGREDIENT:

Azoxystrobin: methyl(*E*)-2-(2-[6-(2-cyanophenoxy)pyrimidin-4-yloxyphenyl]-3-methoxyacrylate\*.....

% BY WT

98.8%

## OTHER INGREDIENTS:.....

1.2%

**TOTAL** 100.0%

\*IUPAC

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

### Manufactured for:

Irvita Plant Protection N.V.  
c/o Makhteshim Agan of North America, Inc.  
3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

EPA Reg. No. 74054-xx

EPA Est. No. XXXXXXXXXX

NET CONTENTS: \_\_\_\_\_ Pounds (Kilos)

### FIRST AID

#### IF ON SKIN OR CLOTHING:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15 to 20 minutes.
- Call a poison control center or doctor for treatment advice.

#### IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance; then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

#### IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.
- Remove contact lenses, if present, after the first 5 minutes; then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

**Have the product container or label with you when calling a poison control center or doctor or going for treatment.**

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION.** Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

The active ingredient, azoxystrobin, in this product can be persistent for several months or longer. Azoxystrobin has degradation products which have properties similar to chemicals which are known to leach through soil to groundwater under certain conditions as a result of labeled use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

This pesticide is toxic to freshwater and estuarine/marine fish and aquatic invertebrates. Keep out of lakes, streams, ponds, tidal marshes, or estuaries. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Notify state and/or federal authorities immediately if you observe any adverse environmental effects due to the use of this product.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product which may be labeled for use patterns as listed on this label.

**For Manufacturing Use Only into a Fungicide for the Following Uses:**

1. Terrestrial Nonfood: Uses on golf courses, lawns, and landscape areas around residential, institutional, public, commercial, and industrial buildings, parks, recreational areas, and athletic fields; uses on ornamentals grown in container, bench, flat, plug, bed, or in the field, in greenhouses, shade houses, outdoor nurseries, retail nurseries, and other landscape areas; and
2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
3. Uses for experimental purposes that are in compliance with USEPA requirements.



### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, cover spill with moist sand, soil, or sawdust. Transfer to a container for disposal. Wash the spillage area with water. Washings must be prevented from entering surface water drains.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

**CONTAINER HANDLING: Nonrefillable Container (flexible-bag-all weights):** Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

### LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Ivita Plant Protection, N.V.. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, Ivita Plant Protection, N.V. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Ivita Plant Protection, N.V. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Ivita Plant Protection, N.V. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Ivita Plant Protection, N.V.'s election, the replacement of product.

FUNGICIDE FOR MANUFACTURING USE ONLY

**% BY WT**

98.8%

.1.2%

TOTAL	100.0%
-------	--------

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

c/o Makhteshim Agan of North America, Inc.  
3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

EPA Est. No.

NET CONTENTS: Pounds (Kilos)

Page 1 of 3

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION.** Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

The active ingredient, azoxystrobin, in this product can be persistent for several months or longer. Azoxystrobin has degradation products which have properties similar to chemicals which are known to leach through soil to groundwater under certain conditions as a result of labeled use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

This pesticide is toxic to freshwater and estuarine/marine fish and aquatic invertebrates. Keep out of lakes, streams, ponds, tidal marshes, or estuaries. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Notify state and/or federal authorities immediately if you observe any adverse environmental effects due to the use of this product.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product which may be labeled for use patterns as listed on this label.

**For Manufacturing Use Only into a Fungicide for the Following Uses:**

1. Terrestrial Nonfood: Uses on golf courses, lawns, and landscape areas around residential, institutional, public, commercial, and industrial buildings, parks, recreational areas, and athletic fields; uses on ornamentals grown in container, bench, flat, plug, bed, or in the field, in greenhouses, shade houses, outdoor nurseries, retail nurseries, and other landscape areas; and
2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
3. Uses for experimental purposes that are in compliance with USEPA requirements.

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, cover spill with moist sand, soil, or sawdust. Transfer to a container for disposal. Wash the spillage area with water. Washings must be prevented from entering surface water drains.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

**CONTAINER HANDLING: Nonrefillable Container (flexible-bag-all weights):** Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

## LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Irvita Plant Protection, N.V.. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, Irvita Plant Protection, N.V. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Irvita Plant Protection, N.V. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Irvita Plant Protection, N.V. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Irvita Plant Protection, N.V.'s election, the replacement of product.

# DATA PACKAGE BEAN SHEET

Date: 22-Aug-2013

Page 1 of 2

Decision #: 477664

DP #: (411748)

PRIA

Parent DP #:

Submission #: 933747

E-Sub #:

## \*\*\* Registration Information \*\*\*

Registration: 74054-T - AZOXYSTROBIN TECHNICAL NC

Company: 74054 - IRVITA PLANT PROTECTION N.V.

Risk Manager: RM 20 - William Cutchin - (703) 305-7990 Room# PY1 S-7828

Risk Manager Reviewer: Shaunta Hill SHILL04

Sent Date: \_\_\_\_\_

PRIA Due Date: 06-Mar-2014

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (R333) NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OI

Ingredients: 128810, Azoxystrobin(96%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 13-May-2013

Due Back: \_\_\_\_\_

DP Ingredient: 128810, Azoxystrobin

DP Title: \_\_\_\_\_

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: \_\_\_\_\_

Assigned To

Date In

Date Out

Organization: RD / TRB

15-May-2013

Last Possible Science Due Date: 06-Mar-2014

Team Name: TOX

Science Due Date: \_\_\_\_\_

Reviewer Name: \_\_\_\_\_

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

## \*\*\* Data Package Instructions \*\*\*

- TRB/AT.
1. Please provide a PRIA 3 - technical screen for the pending application by 7/15/13. If any deficiencies are noted, please provide a technical screen memo.
  2. Please provide an analysis/determination of acceptability for the attached acute tox data by the listed LSDD. Please also determine the acceptability of the attached basic CSF.
- Copies of the incoming letter, CSF, transmittal form and data matrix are attached for your reference/review.
- If you have any questions, please let me know.
- Thank you Shaunta Hill: 347-8961 or hill.shaunta@epa.gov.

*All documents  
are present  
MTH  
38  
7-20-13*

**CONFIDENTIAL**  
\*Claimed confidential by submitter\*

74054-T

## Memorandum

Date: 7/19/13

To: PM 20, *response to 75day letter -* *pls assign to* *er*

From: Information Services Brai *SH*

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions, please contact Teresa I

*just assigned to Shaunta H.*

This is a:

- ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission

# **Administrative Documents**





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

July 18, 2013

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

MAKHTESHIM AGAN OF NORTH AMERICA, INC.  
IRVITA PLANT PROTECTION N.V.  
3120 HIGHWOODS BLVD., SUITE 100  
RALEIGH, NC 27604

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 08-JUL-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# Receipt for Section 3

S: 938025

Resubmission: ☒ Yes ☐ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: New Registration

Billable: ☐ Yes ☒ No

Company: 74054 IRVITA PLANT PROTECTION N.V. ☒

Risk Manager: Registration Division, Risk Management Team 20

Product #: 74054-T Product Name: AZOXYSTROBIN TECHNICAL NC

Override#:

Me Too Section3: 100-1120 Me Too Product Name: AZOXYSTROBIN DRY TECHNICAL MANUFAC

Application Date: 02-Jul-2013 ☒ OPP Rec'd Date: 08-Jul-2013 ☒

Front End Date: 09-Jul-2013 ☒ Risk Manager Send Date: 09-Jul-2013 ☒

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

response to EPA deficiency letter dated 6/6/13

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit

\* Claimed confidential by submitter\*

## **BIBLIOGRAPHY OF SUBMITTED STUDIES**

**Name and Address of Submitter:** Irvita Plant Protection N.V.  
c/o Makhteshim Agan of North America, Inc.  
3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

**Product(s):** Azoxystrobin Technical NC

**EPA Registration No:** 74054-T (OPP Decision#477664)

**Purpose of Submission:** Submission of revised Production Report (MRID 49102601) in response to EPA's letter dated 6-6-2013

**Date of Submission:** July 2, 2013

<b>Volume Number</b>	<b>Study Title</b>	<b>Laboratory, ID Number</b>	<b>OPPTS Guideline Reference Number</b>	<b>EPA MRID Number (Reserved for EPA Use)</b>
1 of 9	<b>Azoxystrobin Technical NC</b> Product Identity and Composition Description of Materials Used Description of Production Process Discussion of the Formation of Impurities Certified Limits Enforcement Analytical Method Submittal of Sample	Ceres 130702	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800 & 830.1900	<b>49167601</b>

## Hill, Shaunta

---

**From:** Hill, Shaunta  
**Sent:** Thursday, June 06, 2013 4:45 PM  
**To:** 'bertvolger@ceresinternational.com'  
**Subject:** Application Deficiency 74054-T. OPP Decision Number: 477664  
**Attachments:** [Untitled].pdf

Bert Volger  
Irvita Plant Protection N.V.  
c/o Makhteshim Agan of North America, Inc.  
3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

Dear Mr. Volger,

The Agency has received and begun its in-depth review of the subject application and has determined that further information is needed. Please see the attached letter for details of the application deficiencies. Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed. Please note that the Agency cannot proceed with the review until this information is available and submitted to the Agency.

If you have any questions, please feel free to contact me.

Regards,

\*\*\*\*\*

Shaunta Hill, Ph. D  
U.S. EPA :Office of Chemical Safety and Pollution Prevention  
Registration Division/Fungicide Branch  
1200 Pennsylvania Avenue, NW (7504P)  
Washington, DC 20460

Tel: 703.347.8961 | Fax: 703.305.6920  
E-mail: [hill.shaunta@epa.gov](mailto:hill.shaunta@epa.gov)  
URL Address: [www.epa.gov/pesticides](http://www.epa.gov/pesticides)

*Response due  
8/20/13*

**ROUTING AND TRANSMITTAL SLIP****Date:** June 6, 2013**TO:***(Name, office symbol,  
room number, building, Agency/Post)*

Signature

Date

1. Driss Benmhend  
Acting Product Manager 20

JUN 06 2013

2.

3.

4.

5.

**Action (s)**

<input checked="" type="checkbox"/>	Approval		For Clearance		Note and Return
	As Requested		For Concurrence		Per Conversation
	Circulate		For Correction		Prepare Reply
	Comment		For Your Information		See Me
	Coordination		Investigate	<input checked="" type="checkbox"/>	Signature
	File		Justify		

**REMARKS****PRIA 75-day letter****Azoxystrobin** (PRIA III application request)

The noted deficiencies were discovered under the technical screen period. As they are not "show stoppers", a 75-day letter will be issued in lieu of a 10-day letter.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions.

**FROM:** *(Name, org. symbol, Agency/Post)*

Room No.— Bldg.

S-7325 - Potomac Yard

Shaunta Hill, OPP/FB  
One Potomac Yard/EPA 7505P

Phone No.

(703) 347-8961



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

Bert Volger  
Irvita Plant Protection N.V.  
c/o Makhteshim Agan of North America, Inc.  
3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

JUN 06 2013

OPP Decision Number: 477664

**Subject: Application Deficiency**  
Azoxystrobin Technical NC  
EPA File Symbol: 74054-T  
Application Date: 04-04-2013  
EPA Receipt Date: 04-15-2013

Dear Mr. Volger,

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

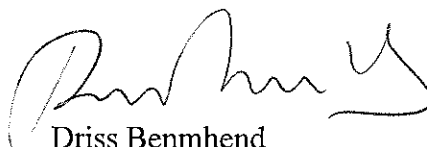
The deficiencies identified in the Agency's review at this time are as follows.

1. The submitted basic CSF is not representative of the approved form (boxes 7-9 are excluded). Please utilize the approved CSF form (8570-4) available at <http://www.epa.gov/opprd001/forms/> and provide information for boxes 7, 8 and 9.
2. The proposed nominal concentration on the Basic CSF differs from the 5-batch analysis of the active ingredient purity.
3. MSDS for the starting material used in step 2 of the production process must be provided.
4. Relative to the submitted group A product chemistry data, the chemical equation and structure diagrams must be corrected for the production process. The chemical equation and structure for the impurities must also be corrected.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

Please respond to this letter within 75 days of the stamped date by contacting Shaunta Hill (hill.shaunta@epa.gov, 703-347-8961) or Driss Benmhend (Benmhend.driss@epa.gov, 703-308-9525) during the hours of 9 am to 4 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Driss Benmhend  
Acting Product Manager 20  
Fungicide Branch  
Registration Division (7504P)





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

SUB DP BARCODE: 411898; PARENT DP BARCODE No.: D411747; FILE SYMBOL No.: 74054-T  
(screen); PRODUCT NAME: Azoxystrobin Technical NC; DECISION No.: 477664; PC Code(s): 128810;  
ACTION CODE: R333; FOOD Use: No

DATE OUT: May 20, 2013

SUBJECT: Completeness check Screening for TGAI/MUP

Product Name: Azoxystrobin Technical NC

FROM: Shyam Mathur,  
Product Chemistry Team Leader  
Technical Review Branch/RD (7505P)

*SPM 5/20/13*

TO: Shaunta Hill / William Cutchin, PM 20  
Fungicide Branch / RD (7505P)

Company Name: Ivita Plant protection N.V  
Formulation Type: Fungicide

Results of completeness check screen of Azoxystrobin Technical NC

File No./ Reg. No	Product Name	Group A Data Submitted		Group B Data Submitted		CSF		Label
		Yes	No	Yes	No	Yes	No	
74054-T	Azoxystrobin Technical NC	+	+ 830.1600	+		+ Basic CSF (4-10-13)		Yes

SUMMARY OF FINDINGS & CONCLUSIONS:

1. Basic CSF (dated 04-10-2013) representing new production site in [REDACTED]

- Box #7 (density), Box #8 (pH) and Box #9 (Flash point) are missing from the CSF.
- Proposed Nominal concentration (96%) on the CSF is different than 5 batch analysis of the AI showing 98.8% purity.

2. Submitted group A product chemistry data to support the proposed basic CSF.

- 830.1600(starting materials): Missing MSDS for starting material [REDACTED] used in Step 2 of production process.
- 830.1620 (production process): Chemical equation & structures diagrams representing the production process are not correctly given.
- 830.1670 (discussion on impurities): Chemical equation & structures of impurities diagrams are not correctly given.

\*Commercial/financial information may be entitled to confidential treatment\*  
\*Manufacturing process information may be entitled to confidential treatment\*

 COPY

## DATA PACKAGE BEAN SHEET

Date: 20-May-2013

Page 1 of 1

Decision #: 477664

DP #: (411898)

PRIA

Parent DP #: 411747

Submission #: 933747

E-Sub #:

### \*\*\* Registration Information \*\*\*

Registration: 74054-T - AZOXYSTROBIN TECHNICAL NC

Company: 74054 - IRVITA PLANT PROTECTION N.V.

Risk Manager: RM 20 - William Cutchin - (703) 305-7990 Room# PY1 S-7828

Risk Manager Reviewer: Shyam Mathur SMATHUR

Sent Date:

PRIA Due Date: 06-Mar-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R333) NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OI

Ingredients: 128810, Azoxystrobin(96%)

*Screen  
5-20-13*

### \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 20-May-2013

Due Back:

DP Ingredient: 128810, Azoxystrobin

DP Title:

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: 411747

Assigned To

Date In

Date Out

Organization: RD / TRB

20-May-2013

Last Possible Science Due Date: 06-Mar-2014

Team Name: CHEM

20-May-2013

Science Due Date:

Reviewer Name: Mathur, Shyam

20-May-2013

20-May-2013

Sub Data Package Due Date:

Contractor Name:

### \*\*\* Studies Sent for Review \*\*\*

No Studies

### \*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

### \*\*\* Data Package Instructions \*\*\*

No Instructions

## Hill, Shaunta

---

**From:** Hashim, Masih  
**Sent:** Wednesday, May 29, 2013 9:46 AM  
**To:** Hill, Shaunta  
**Cc:** Redden, John; Keigwin, Tracy  
**Subject:** FW: Screening for #74054-T Azoxystrobin Technical NC D411748

TRB has received a package of the proposed (subject) product for acute toxicity evaluation. Initial screening shows that all documents including six tox studies, Company letter, CSF and the product label are present in the package. The package will be returned to the File Drawer (Document Room) today.

Tox review of each study will determine if it is acceptable in accordance with the

Agency requirements. DER for this product will be issued before the (PRIA) Science due date, may 6, 2014.

# AZOXYSTROBIN TECHNICAL NC

FUNGICIDE FOR MANUFACTURING USE ONLY

**ACTIVE INGREDIENT:****% BY WT**

Azoxystrobin: methyl(*E*)-2-(2-[6-(2-cyanophenoxy)pyrimidin-4-yloxyphenyl]-3-methoxyacrylate\* ..... 96.0%

**OTHER INGREDIENTS:** ..... 4.0%

**TOTAL** 100.0%

\*IUPAC

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

**Manufactured for:**

Irvita Plant Protection N.V.  
c/o Makhteshim Agan of North America, Inc.  
3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

EPA Reg. No. 74054-xx

EPA Est. No. XXXXXXXXXX

NET CONTENTS: \_\_\_\_\_ Pounds (Kilos)

### FIRST AID

**IF ON SKIN OR CLOTHING:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15 to 20 minutes.
- Call a poison control center or doctor for treatment advice.

**IF INHALED:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance; then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

**IF IN EYES:**

- Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.
- Remove contact lenses, if present, after the first 5 minutes; then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

**Have the product container or label with you when calling a poison control center or doctor or going for treatment.**

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION.** Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

The active ingredient, azoxystrobin, in this product can be persistent for several months or longer. Azoxystrobin has degradation products which have properties similar to chemicals which are known to leach through soil to groundwater under certain conditions as a result of labeled use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

This pesticide is toxic to freshwater and estuarine/marine fish and aquatic invertebrates. Keep out of lakes, streams, ponds, tidal marshes, or estuaries. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Notify state and/or federal authorities immediately if you observe any adverse environmental effects due to the use of this product.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product which may be labeled for use patterns as listed on this label.

**For Manufacturing Use Only into a Fungicide for the Following Uses:**

1. Terrestrial Nonfood: Uses on golf courses, lawns, and landscape areas around residential, institutional, public, commercial, and industrial buildings, parks, recreational areas, and athletic fields; uses on ornamentals grown in container, bench, flat, plug, bed, or in the field, in greenhouses, shade houses, outdoor nurseries, retail nurseries, and other landscape areas; and
2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
3. Uses for experimental purposes that are in compliance with USEPA requirements.

### **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, cover spill with moist sand, soil, or sawdust. Transfer to a container for disposal. Wash the spillage area with water. Washings must be prevented from entering surface water drains.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

**CONTAINER HANDLING: Nonrefillable Container (flexible-bag-all weights):** Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

### **LIMITATION OF WARRANTY AND LIABILITY**

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Irvita Plant Protection, N.V.. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, Irvita Plant Protection, N.V. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Irvita Plant Protection, N.V. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Irvita Plant Protection, N.V. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Irvita Plant Protection, N.V.'s election, the replacement of product.

# Completion of 21-Day Content Screen

PM- 20

EPA Reg. # (File Symbol) 74054-T

Decision # D 477664

Data package delivered to  
you on 4/26/13.  
(date)

Jacket/Mini-jacket will be  
transferred to you today.  
(Pick up from Document Center)

Thank you,

Registration Division's 21-Day Content Team

## Memorandum

Date: 4 / 24 / 13

To: PM 20, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

April 23, 2013

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

MAKHTESHIM AGAN OF NORTH MERICA, INC.  
IRVITA PLANT PROTECTION N.V.  
3120 HIGHWOODS BLVD., SUITE 100  
RALEIGH, NC 27604

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 15-APR-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# Receipt for Section 3

S: 933747

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 74054 IRVITA PLANT PROTECTION N.V.

V

Risk Manager: Registration Division, Risk Management Team 20

Product #: 74054-T Product Name: AZOXYSTROBIN TECHNICAL NC

Override:

Me Too  
Section3: 100-1120

Me Too  
Product Name: AZOXYSTROBIN DRY TECHNICAL MANUFAC

Application Date: 04-Apr-2013



OPP Rec'd Date: 15-Apr-2013



Front End Date: 16-Apr-2013



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Application for new product registration

New Ingredient

Request Date:

New Ingredient

Received Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

Paper Label

View/Edit

8:00 AM



**BIBLIOGRAPHY OF SUBMITTED STUDIES**

**Name and Address of Submitter:** Irvita Plant Protection N.V.  
 c/o Makhteshim Agan of North America, Inc.  
 3120 Highwoods Blvd., Suite 100  
 Raleigh, NC 27604

**Product(s):** Azoxystrobin Technical NC

**EPA Registration No:** 74054-to be assigned

**Purpose of Submission:** Submission of data in support of the application for “me-too”  
 registration of Azoxystrobin Technical NC

**Date of Submission:** April 10, 2013

<b>Volume Number</b>	<b>Study Title</b>	<b>Laboratory, ID Number</b>	<b>OPPTS Guideline Reference Number</b>	<b>EPA MRID Number (Reserved for EPA Use)</b>
1 of 9	<b>Azoxystrobin Technical NC</b> Product Identity and Composition Description of Materials Used Description of Production Process Discussion of the Formation of Impurities Certified Limits Enforcement Analytical Method Submittal of Sample	Ceres 130311	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800 & 830.1900	<b>49102601</b>
2 of 9	<b>Azoxystrobin Technical NC</b> Preliminary Analysis and Enforcement Analytical Method of Azoxystrobin TGAI (Validation of Analytical Methodology for the Assay of Active Ingredient and Related Significant Impurities and Subsequent Five-Batch Analysis of Azoxystrobin TGAI)	NC-2010-007	830.1700, 830.1750 and 830.1800	<b>49102602</b>

<b>Volume Number</b>	<b>Study Title</b>	<b>Laboratory, ID Number</b>	<b>OPPTS Guideline Reference Number</b>	<b>EPA MRID Number (Reserved for EPA Use)</b>
3 of 9	<b>Azoxystrobin Technical NC</b> Chemical and Physical Characterization of Azoxystrobin TGAI: Color, Physical State, Odor, Stability, Oxidation/Reduction, pH, UV-Vis, Melting Point, Density, Dissociation Constant, Partition Coefficient and Water Solubility	NC-2010-008	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7570, and 830.7840	<b>49102603</b>
4 of 9	<b>Azoxystrobin Technical NC</b> Acute Oral Toxicity Study of Azoxystrobin TGAI in Rats	JAI # 401-1-01-5259	830.7200	<b>49102604</b>
5 of 9	<b>Azoxystrobin Technical NC</b> Acute Dermal Toxicity Study of Azoxystrobin TGAI in Rats	JAI # 403-1-01-5260	830.7570	<b>49102605</b>
6 of 9	<b>Azoxystrobin Technical NC</b> Acute Inhalation Study of Azoxystrobin TGAI in Rats	JAI # 403-1-01-5260	830.7840	<b>49102606</b>
7 of 9	<b>Azoxystrobin Technical NC</b> Acute Eye Irritation Study of Azoxystrobin TGAI in Rabbits	JAI #407-1-01-5263	830.7840	<b>49102607</b>
8 of 9	<b>Azoxystrobin Technical NC</b> Acute Dermal Irritation Study of Azoxystrobin TGAI in Rabbits	JAI #406-1-01-5262	830.7950	<b>49102608</b>
9 of 9	<b>Azoxystrobin Technical NC</b> Skin Sensitization Test of Azoxystrobin TGAI in Guinea Pigs (Maximization Test)	JAI #408-1-01-5264	870.1100	<b>49102609</b>

**21-Day Screen Completed by**  
**Contractor**

**21-Day Expires on** 5-6-13

**Jacket #** 74054-T  
**MRID#** 491026

**Content Screen:** Recommend to Pass/Fail

**11-3 Review:** Pass/Fail/NA

**Overall Status:** Recommend to Pass/Fail

**Transfer This Jacket to:**

STEPHEN SETTABLE

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 4/15/13

Experts In-Processing Signature: MP Date 4/18/13

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>74054-T</u>		EPA Receipt Date: <u>4/15/13</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)		X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	<div style="display: flex; justify-content: space-between;"> <div>yes</div> <div>no</div> </div> <div style="text-align: center; margin-top: 5px;">No inerts</div>			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)		X		
	Certificate and data matrix consistent		X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<div style="display: flex; justify-content: space-between;"> <div>yes</div> <div>no</div> </div>			
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)				X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)		X		
5	a) Selective Method (Fee category experts use)	<div style="display: flex; justify-content: space-between;"> <div>yes</div> <div>no</div> </div> <div style="text-align: center; margin-top: 5px;">X</div>			
	b) Cite-All (Fee category experts use)	<div style="display: flex; justify-content: space-between;"> <div></div> <div></div> </div>			
	c) Applicant owns all data (Fee category experts use)	<div style="display: flex; justify-content: space-between;"> <div></div> <div></div> </div>			
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)		X		
7	Is the data package consistent with PR Notice 86-5		X		
8	Notice of Filing included with petitions				X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

**Comments:**

- \* Studies panned PRN 11-03 review.
- \* CSF was missing in the application package. The registrant send it when contacted.
- \* Active and impurities only; no inserts to review.
- \* Jacket passed.

AB

MRID: 491026



\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Bert Volger  
Phone #: 610-793-3222  
Email: bertvolger@ceresinternational.com

First Call/Initials: AB

Date: 04-23-13

Time: 12:53 PM

Second Call/Initials:

Date:

Time:

This is Aswathy Balan, EPA contractor.

I'm calling regarding your submission in support of

Reg # 14054-T.

Passed

We have found the following deficiencies regarding:

PR Notice 2011-3: Yes or No

Volume/Study Title:

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

\* CSF missing

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn: Aswathy Balan.

Second Call/Email:

If we do not receive the corrections by \_\_\_\_\_, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.

## Balan, Aswathy

---

**From:** Bert Volger [bertvolger@ceresinternational.com]  
**Sent:** Tuesday, April 23, 2013 1:04 PM  
**To:** Balan, Aswathy  
**Cc:** Ashe, Anthony  
**Subject:** RE: Submission to EPA: Product Azoxystrobin Technical NC (Reg# 74054-T)  
**Attachments:** 130410 Azoxystrobin Technical NC (74054-xx) -CSF -subm.pdf

Dear Aswathy,

Sorry for the oversight; here is the CSF.

Kind regards,  
Bert

Ceres International LLC  
1087 Heartsease Drive  
West Chester, PA 19382  
Ph. 610-793-3222  
[bertvolger@ceresinternational.com](mailto:bertvolger@ceresinternational.com)

**From:** Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]  
**Sent:** Tuesday, April 23, 2013 12:53 PM  
**To:** [bertvolger@ceresinternational.com](mailto:bertvolger@ceresinternational.com)  
**Cc:** Ashe, Anthony  
**Subject:** Submission to EPA: Product Azoxystrobin Technical NC (Reg# 74054-T)

Dear Mr. Volger,

This email is regarding your Application for Registration of the product Azoxystrobin Technical NC (Reg# 74054-T). The CSF form is missing in your application package. You can send it to me via email or fax to 703-305-5060. If you have any questions, do not hesitate to contact me.

Thanks,

*Aswathy Balan  
EPA Contractor  
2777 S. Crystal Drive, S4811  
Arlington, VA 22202  
Ph: 703-347-8787  
Fax: 703-305-5060*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

April 17, 2013

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-477664  
EPA File Symbol or Registration Number: 74054-T  
Product Name: AZOXYSTROBIN TECHNICAL NC  
EPA Receipt Date: 15-Apr-2013  
EPA Company Number: 74054  
Company Name: IRVITA PLANT PROTECTION N.V.

BERT VOLGER, Ph.D.  
MAKHTESHIM AGAN OF NORTH MERICA, INC.  
IRVITA PLANT PROTECTION N.V.  
3120 HIGHWOODS BLVD., SUITE 100  
RALEIGH, NC 27604-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R333

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL FORM;CITE-ALL OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m/26", is written over the word "Sincerely,".

Front End Processing Staff  
Information Technology & Resources Management Division

**Fee for Service**

{933747F~

This package includes the following

- ☒ New Registration
- ☐ Amendment

- ☒ Studies?    ☐ Fee Waiver?
- ☐ volpay    % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 20

Receipt No.

S- 933747

EPA File Symbol/Reg. No.

74054-T

Pin-Punch Date:

4/15/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: 2333

Granted: R333

Amount Due: \$ 17,923.00

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: M. Lewis

Date: 4/17/13

Remarks:

SIM CLINIC - CITAS 100-1120

NO CSF IN PACKAGE

DS 4/20/13  
No Sim Clin,  
as Acute tox data provided

# Receipt for Section 3

S: 933747

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 74054 IRVITA PLANT PROTECTION N.V. V

Risk Manager: Registration Division, Risk Management Team 20

Product #: 74054-T Product Name: AZOXYSTROBIN TECHNICAL NC

Override#:

Me Too Section3: 100-1120 Me Too Product Name: AZOXYSTROBIN DRY TECHNICAL MANUFAC

Application Date: 04-Apr-2013

OPP Rec'd Date: 15-Apr-2013

Front End Date: 16-Apr-2013

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Application for new product registration

New Ingredient Request Date  
New Ingredient Received Date

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study	
Paper Label	

View/Edit



-----Original Message-----

From: [paygovadmin@mail.doc.twai.gov](mailto:paygovadmin@mail.doc.twai.gov) [<mailto:paygovadmin@mail.doc.twai.gov>]

Sent: Wednesday, April 10, 2013 1:47 PM

To: Shannon Cooley

Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at [pay.gov.clev@clev.frb.org](mailto:pay.gov.clev@clev.frb.org).

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25A9K3CJ

Agency Tracking ID: 74433826196

Transaction Type: Sale

Transaction Date: Apr 10, 2013 2:46:51 PM

Account Holder Name: Anne Turnbough

Transaction Amount: \$17,993.00

Billing Address: 5903 Genoa Red Bluff Rd.

City: Pasadena

State/Province: TX

Zip/Postal Code: 77507

Country: USA

Card Type: MasterCard

Card Number: \*\*\*\*\*400S

Decision Number:

Registration Number:

Company Name: Control Solutions, Inc.

Company Number: 53883

Action Code: R333

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



United States  
**Environmental Protection Agency**  
 1200 Pennsylvania Avenue, N.W.  
 Washington, DC 20460-0001

☒ **Registration**  
☐ **Amendment**  
☐ **Other**

OPP Identifier Number

### Application for Pesticide – Section I

1. Company/Product Number  Irvita Plant Protection N.V./74054-xx	2. EPA Product Manager  Cynthia Giles-Parker	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/ Product (Name) Azoxystrobin Technical NC	PM # 20	
5. Name and Address of Applicant (Include ZIP Code) Irvita Plant Protection N.V. c/o Makhteshim Agan of North America, Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604 <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(b)(i) my product is similar or identical in composition and labeling to:  EPA Reg. No. 100-1120 Product Name: Azoxystrobin Dry Technical Manufacturing Use Concentrate Fungicide

### Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Application for new product registration containing a new manufacturing-use product with a unregistered source of an active ingredient (Azoxystrobin). Submission of PC, and Acute Toxicity data in support of this application.

FEE CATEGORY: R333 (New product; MUP or end use product with unregistered source of active ingredient; requires science data review; Cite-all or selective data citation where applicant owns all required data; 10 months review process). FEE DUE: \$ 17,993.-

EMAIL: bertvolger@comcast.net

### Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
<b>*Certification must be submitted</b>		If "Yes" Unit Packaging Wt.	No. Per Container	If "Yes" Packaging Wt.	No. Per Container
3. Location of Net Contents Information  <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container  1 pint to 1 gallon		5. Location of Label Directions  <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Other Printed; Self-adhesive					

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name Bert Volger, Ph.D.	Title Agent for Irvita Plant Protection N.V.	Telephone No. (Include Area Code) 610-793-3222
----------------------------	--	---

### Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Agent for Irvita Plant Protection N.V.	6. Date Application Received (Stamped)
4. Typed Name Bert Volger, Ph.D.	5. Date 4-10-2013	



**BIBLIOGRAPHY OF SUBMITTED STUDIES**

**Name and Address of Submitter:** Irvita Plant Protection N.V.  
 c/o Makhteshim Agan of North America, Inc.  
 3120 Highwoods Blvd., Suite 100  
 Raleigh, NC 27604

**Product(s):** Azoxystrobin Technical NC

**EPA Registration No:** 74054-to be assigned

**Purpose of Submission:** Submission of data in support of the application for “me-too”  
 registration of Azoxystrobin Technical NC

**Date of Submission:** April 10, 2013

<b>Volume Number</b>	<b>Study Title</b>	<b>Laboratory, ID Number</b>	<b>OPPTS Guideline Reference Number</b>	<b>EPA MRID Number (Reserved for EPA Use)</b>
1 of 9	<b>Azoxystrobin Technical NC</b> Product Identity and Composition Description of Materials Used Description of Production Process Discussion of the Formation of Impurities Certified Limits Enforcement Analytical Method Submittal of Sample	Ceres 130311	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800 & 830.1900	
2 of 9	<b>Azoxystrobin Technical NC</b> Preliminary Analysis and Enforcement Analytical Method of Azoxystrobin TGAI (Validation of Analytical Methodology for the Assay of Active Ingredient and Related Significant Impurities and Subsequent Five-Batch Analysis of Azoxystrobin TGAI)	NC-2010-007	830.1700, 830.1750 and 830.1800	

<b>Volume Number</b>	<b>Study Title</b>	<b>Laboratory, ID Number</b>	<b>OPPTS Guideline Reference Number</b>	<b>EPA MRID Number (Reserved for EPA Use)</b>
3 of 9	<b>Azoxystrobin Technical NC</b> Chemical and Physical Characterization of Azoxystrobin TGAI: Color, Physical State, Odor, Stability, Oxidation/Reduction, pH, UV- Vis, Melting Point, Density, Dissociation Constant, Partition Coefficient and Water Solubility	NC-2010-008	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7570, and 830.7840	
4 of 9	<b>Azoxystrobin Technical NC</b> Acute Oral Toxicity Study of Azoxystrobin TGAI in Rats	JAI # 401-1-01-5259	830.7200	
5 of 9	<b>Azoxystrobin Technical NC</b> Acute Dermal Toxicity Study of Azoxystrobin TGAI in Rats	JAI # 403-1-01-5260	830.7570	
6 of 9	<b>Azoxystrobin Technical NC</b> Acute Inhalation Study of Azoxystrobin TGAI in Rats	JAI # 403-1-01-5260	830.7840	
7 of 9	<b>Azoxystrobin Technical NC</b> Acute Eye Irritation Study of Azoxystrobin TGAI in Rabbits	JAI #407-1-01-5263	830.7840	
8 of 9	<b>Azoxystrobin Technical NC</b> Acute Dermal Irritation Study of Azoxystrobin TGAI in Rabbits	JAI #406-1-01-5262	830.7950	
9 of 9	<b>Azoxystrobin Technical NC</b> Skin Sensitization Test of Azoxystrobin TGAI in Guinea Pigs (Maximization Test)	JAI #408-1-01-5264	870.1100	



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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address and Telephone Number

Irvita Plant Protection N.V.  
 c/o Makhteshim Agan of North America, Inc.  
 3120 Highwoods Blvd., Suite 100  
 Raleigh, NC 27604  
 919-256-9300

EPA Registration Number/File Symbol

74054-xx

Active Ingredient(s) and/or Representative Test Compound(s)

Azoxystrobin

Date

4-10-2013

General Use Pattern(s) [list all those claimed for this product using 40 CFR Part 158]

Non-Food use sites

Product Name

Azoxystrobin Technical NC

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**Section I: Method of Data Support**

(Check only one method)

☐ I am using the cite-all method of support and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method) and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**Section II: General Offer-to-Pay**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation to other persons with regard to the approval of this application to the extent required by FIFRA.

**Section III: Certification**

I hereby certify that this application for registration, this form for reregistration or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered: (i) to pay compensation to the extent required by Sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with Sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

4-10-2013

Typed or Printed Name and Title

Bert Volger, Ph.D.,  
 Agent for Irvita Plant Protection N.V.

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## DATA MATRIX

Date: April 9, 2013			EPA Reg. No./File Symbol: 74054 -xxx		Page 1 of 10
Applicant's/Registrant's Name & Address: Ivita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604			Product:  Azoxystrobin Technical NC		
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Specific Data Requirements</b>					
830.1550	Product Identity and Composition		Ivita Plant Protection N.V.	OWN	
830.1600	Description of Materials Used to Produce the Product		Ivita Plant Protection N.V.	OWN	
830.1620	Description of Production Process		Ivita Plant Protection N.V.	OWN	
830.1650	Description of Formulation Process				Not Required <sup>1</sup>
830.1670	Discussion of Formation of Impurities		Ivita Plant Protection N.V.	OWN	
830.1700	Preliminary Analysis		Ivita Plant Protection N.V.	OWN	
830.1750	Certified Limits		Ivita Plant Protection N.V.	OWN	
830.1800	Enforcement Analytical Method		Ivita Plant Protection N.V.	OWN	
830.6302	Color		Ivita Plant Protection N.V.	OWN	
830.6303	Physical State		Ivita Plant Protection N.V.	OWN	
830.6304	Odor		Ivita Plant Protection N.V.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions		Ivita Plant Protection N.V.	OWN	

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## DATA MATRIX

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Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604			Product:  Azoxystrobin Technical NC		
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/Reduction: Chemical Incompatibility		Irvita Plant Protection N.V.	OWN	
830.6315	Flammability				Not Required <sup>2</sup>
830.6316	Explosibility				Not Required <sup>2</sup>
830.6317	Storage Stability		Irvita Plant Protection N.V.	OWN	
830.6319	Miscibility				Not Required <sup>2</sup>
830.6320	Corrosion Characteristics		Irvita Plant Protection N.V.	OWN	
830.6321	Dielectric Breakdown Voltage				Not Required <sup>2</sup>
830.7000	pH		Irvita Plant Protection N.V.	OWN	
830.7050	UV/Visible Absorption		Irvita Plant Protection N.V.	OWN	
830.7100	Viscosity				Not Required <sup>2</sup>
830.7200	Melting Point/Melting Range		Irvita Plant Protection N.V.	OWN	
830.7220	Boiling Point/Boiling Range				Not Required <sup>3</sup>
830.7300	Density/Relative Density/Bulk Density		Irvita Plant Protection N.V.	OWN	
830.7370	Dissociation Constants in Water		Irvita Plant Protection N.V.	OWN	
830.7520	Particle Size, Fiber Length, and Diameter Distribution				Not Required <sup>2</sup>
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method		Irvita Plant Protection N.V.	OWN	



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Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604			Product:  Azoxystrobin Technical NC		
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method		Irvita Plant Protection N.V.	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure		Irvita Plant Protection N.V.	OWN	
870.1100	Acute Oral Toxicity: Rat		Irvita Plant Protection N.V.	OWN	
870.1200	Acute Dermal Toxicity: Rat		Irvita Plant Protection N.V.	OWN	
870.1300	Acute Inhalation Toxicity: Rat		Irvita Plant Protection N.V.	OWN	
870.2400	Primary Eye Irritation: Rabbit		Irvita Plant Protection N.V.	OWN	
870.2500	Primary Dermal Irritation		Irvita Plant Protection N.V.	OWN	
870.2600	Dermal Sensitization		Irvita Plant Protection N.V.	OWN	
<b>Generic Data Requirements</b>					
850.2100	Acute Avian Oral Toxicity	Cite-All		PAY	

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Applicant's/Registrant's Name & Address: Invita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604			Product:  Azoxystrobin Technical NC		
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2200	Acute Avian Dietary Toxicity	Cite-All		PAY	
850.2400	Wild Mammal Toxicity				Not required <sup>4</sup>
850.2300	Avian Reproductive Toxicity	Cite-All		PAY	
850.1075	Freshwater Fish Toxicity	43678115 43678120		OLD OLD	See Endnote <sup>5</sup>
850.1010	Freshwater Invertebrate Toxicity	Cite-All		PAY	
850.1075	Estuarine/Marine Fish Toxicity	Cite-All		PAY	
850.1025	Estuarine/Marine Mollusk Toxicity	Cite-All		PAY	
850.1035	Estuarine/Marine Shrimp Toxicity	Cite-All		PAY	
850.1400	Early Life Stage: Fish	Cite-All		PAY	
850.1300	Early Life Stage: Aquatic Invertebrate	Cite-All		PAY	
850.1350	Aquatic Invertebrate Life Cycle (Saltwater)	Cite-All		PAY	
850.1500	Life Cycle Fish				Not Required <sup>6</sup>
850.1710, 850.1730, 850.1850	Aquatic Organisms Bioavailability				Not Required <sup>7</sup>
850.1950	Simulated or actual field testing for aquatic organisms				Not Required <sup>6</sup>

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Applicant's/Registrant's Name & Address: Invita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604		Product: Azoxystrobin Technical NC

Ingredient: Azoxystrobin (CAS No. 131860-33-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.6200	Acute Neurotoxicity (Rat)	Cite-All		PAY	
870.3100	90-Day Oral Toxicity in Rodents	Cite-All		PAY	
870.3150	90-Day Oral Toxicity in Non-Rodents	Cite-All		PAY	
870.3200	21-Day Dermal Toxicity	Cite-All		PAY	
870.3250	90-Day Dermal Toxicity	Cite-All		PAY	
870.3465	90-Day Inhalation Toxicity				Waived <sup>8</sup>
870.6100	28-Day Delayed Neurotoxicity - Hen				Not Required
870.6200	90-Day Subchronic Neurotoxicity -Rat	Cite-All		PAY	
870.4100	Chronic Toxicity Rat	Cite-All		PAY	
870.4200	Carcinogenicity Rat	Cite-All		PAY	
870.4200	Carcinogenicity Mouse	Cite-All		PAY	
870.3700	Prenatal Development Toxicity Studies	Cite-All		PAY	
870.3800	Reproduction and Fertility Effects	Cite-All		PAY	
870.6300	Developmental Neurotoxicity Study				Waived <sup>9</sup>
870.5100	Bacterial Reverse Mutation Test	Cite-All		PAY	
870.5300, 870.5375	In-vitro Mammalian Cell Gene Mutation Test	Cite-All		PAY	
870.5385, 370.5395	In vivo Cytogenetics	Cite-All		PAY	
870.7200	Companion Animal Safety				Not Required

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Date: April 9, 2013	EPA Reg. No./File Symbol: 74054 -xxx	Page 6 of 10
Applicant's/Registrant's Name & Address: Invita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604	Product:  Azoxystrobin Technical NC	

Ingredient: Azoxystrobin (CAS No. 131860-33-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7485	Metabolism and Pharmacokinetics	Cite-All		PAY	
870.7600	Dermal Penetration	Cite-All		PAY	
870.7800	Immunotoxicity	Cite-All		PAY	
850.4100	Tier 1: Seed Germination and Seedling Emergence	43678156 43678157 43678160		OLD OLD OLD	See Endnote <sup>10</sup>
850.4150	Tier 1: Vegetative Vigor	43678158 43678159		OLD OLD	See Endnote <sup>11</sup>
850.4400	Tier 1: Aquatic Plant Growth	43678161 43678162 43678163 43678164 43678165		OLD OLD OLD OLD OLD	See Endnote <sup>12</sup>
875.1100	Dermal Outdoor Exposure		PHED/AHETF	OWN	See Endnote <sup>13</sup>
875.1200	Dermal Indoor Exposure				Not Required
875.1300	Inhalation Outdoor Exposure		PHED/AHETF	OWN	See Endnote <sup>13</sup>

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Date: April 9, 2013	EPA Reg. No./File Symbol: 74054 -xxx	Page 7 of 10
Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604		Product: Azoxystrobin Technical NC

Ingredient: Azoxystrobin (CAS No. 131860-33-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1400	Inhalation Indoor Exposure				Not Required
875.1500	Biological Monitoring				Not Required
875.1600	Data Reporting and Calculations		PHED/AHETF	OWN	See Endnote <sup>13</sup>
875.1700	Product Use Information				See Label
875.2100	Foliar Residue Dissipation	Cite-All		PAY	
875.2200	Soil Residue Dissipation		ARTF/ORETF	OWN	See Endnote <sup>14</sup>
875.2300	Indoor Surface Residue Dissipation				Not Required
875.2400	Dermal Passive Dosimetry Exposure				See Endnote <sup>14</sup>
875.2500	Inhalation Passive Dosimetry Exposure				See Endnote <sup>14</sup>
850.3020	Acute Contact Toxicity: Honey Bee	Cite-All		PAY	
850.3030	Honey Bee Toxicity of Residues on Foliage				Not required
835.2120	Hydrolysis	Cite-All		PAY	
835.2240	Photodegradation in Water	Cite-All		PAY	
835.2410	Photodegradation on Soil	Cite-All		PAY	
835.2370	Photodegradation in Air				Waived <sup>15</sup>

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Date: April 9, 2013			EPA Reg. No./File Symbol: 74054 -12	Page 8 of 10	
Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604			Product:  Azoxystrobin Technical NC		
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.4100	Aerobic Soil Metabolism	Cite-All		PAY	
835.4200	Anaerobic Soil Metabolism	Cite-All		PAY	
835.4300	Anaerobic Aquatic Metabolism	Cite-All		PAY	
835.4400	Aerobic Aquatic Metabolism				Not Required <sup>16</sup>
835.1230, 835.1240	Leaching and Adsorption/Desorption	Cite-All		PAY	
835.1410	Volatility – Laboratory				Waived <sup>17</sup>
835.8100	Volatility – Field				Waived <sup>18</sup>
835.6100	Soil Field Dissipation Study	43678184 43678185 43678186 43678187 44058709 44058711 44058712 44058713		OLD OLD OLD OLD OLD OLD OLD OLD	See Endnote <sup>19</sup>
835.6200	Aquatic Sediment Field Dissipation Study				Not Required <sup>20</sup>
835.6300	Forest Field Dissipation Study				Not Required <sup>21</sup>

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## DATA MATRIX


Date: April 9, 2013			EPA Reg. No./File Symbol: 74054 -xxx	Page 9 of 10	
Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604			Product: Azoxystrobin Technical NC		
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860 series	Residue Chemistry Data requirements				Not required
Irvita Plant Protection, N.V. will make offers-to-pay to the following companies on the data submitters list of Sept. 27, 2012.					
	Cite-All under Selective Method utilized by Irvita Plant Protection, N.V.		Syngenta Crop Protection	PAY	
	Cite-All under Selective Method utilized by Irvita Plant Protection, N.V.		Gustafson LLC	PAY	
	Cite-All under Selective Method utilized by Irvita Plant Protection, N.V.		Loveland Products, Inc.	PAY	
	Cite-All under Selective Method utilized by Irvita Plant Protection, N.V.		Tessenderlo Kerley, Inc.	PAY	
	Cite-All under Selective Method utilized by Irvita Plant Protection, N.V.		Makhteshim Agan of North America, Inc.	PAY	
	Cite-All under Selective Method utilized by Irvita Plant Protection, N.V.		Spray Drift Task Force	OWN	
	Cite-All under Selective Method utilized by Irvita Plant Protection, N.V.		Outdoor Residential Exposure Task Force	OWN	
	Cite-All under Selective Method utilized by Irvita Plant Protection, N.V.		Agricultural Re-Entry Exposure Task Force	OWN	

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## DATA MATRIX

Date: April 9, 2013			EPA Reg. No./File Symbol: 74054 -xxx		Page 10 of 10
Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604			Product: Azoxystrobin Technical NC		
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Cite-All under Selective Method utilized by Irvita Plant Protection, N.V.		FIFRA Endangered Species Task Force, LLC	PAY	
	Cite-All under Selective Method utilized by Irvita Plant Protection, N.V.		Agricultural Handlers Exposure Task Force	OWN	
Signature 			Name and Title: Bert Volger, Ph.D. Agent for Irvita Plant Protection N.V.		Date: 4/9/2013



## Endnotes for Data Matrix for Azoxystrobin Technical NC

- 
- <sup>1</sup> **830.1650** - These data are not required for the registration of a Manufacturing Use Product. See 830.1620 for production process information.
- <sup>2</sup> **830.6315, 830.6316, 830.6319, 830.6321, 830.7100, 830.7520** - Azoxystrobin Technical NC is not flammable (melting point far above 40°C), and is not explosive (chemical structure does not reveal bond groupings known to confer explosibility). Azoxystrobin Technical NC is a solid and not an emulsifiable concentrate and is not to be diluted with petroleum solvents. Therefore, miscibility data are not required for this technical. Azoxystrobin Technical NC is not to be used around electrical equipment and data for dielectric breakdown constant are not required. Azoxystrobin Technical NC is a solid and not a liquid, therefore, viscosity data are not required for this product. Irvita Plant Protection N.V. is seeking a waiver for particle size, fiber length and diameter distribution because Azoxystrobin Technical NC is not water insoluble nor is it a fibrous material.
- <sup>3</sup> **830.7220** - Azoxystrobin Technical NC is a solid and boiling point data are not required for solids. Data for melting point are required for solids. See Guideline 830.7200.
- <sup>4</sup> **850.2400** - Data on wild mammal toxicity are not required; surrogate mammalian toxicity data are available. In addition, no data have been submitted to support this guideline requirement.
- <sup>5</sup> **850.1075** - The studies cited are considered acceptable and satisfy the data requirement as per the Oct. 21, 2009 Preliminary Problem Formulation.
- <sup>6</sup> **850.1500, 850.1950** - These data are not required for the registration of azoxystrobin. No data have been submitted to EPA for these data requirements and these guidelines were not addressed in the Oct. 21, 2009 Preliminary Problem Formulation.
- <sup>7</sup> **850.1710, 850.1730, 850.1850** - This data requirement was waived as per the Oct. 21, 2009 Preliminary Problem Formulation.
- <sup>8</sup> **870.6300** - These data were not required as per the April 30, 2012 Human Health Risk Assessment.
- <sup>9</sup> **870.3465** - This data requirement was waived as per the April 30, 2012 Human Health Risk Assessment.
- <sup>10</sup> **850.4100** - The studies cited are considered acceptable and satisfy the data requirement as per the Oct. 21, 2009 Preliminary Problem Formulation.
- <sup>11</sup> **850.4150** - The studies cited are considered acceptable and satisfy the data requirement as per the Oct. 21, 2009 Preliminary Problem Formulation.
- <sup>12</sup> **850.4400** - MRID numbers 43678164 and 43678165 were listed in the Oct. 21, 2009 Preliminary Problem Formulation as acceptable. MRID numbers 43678161-63 were also cited to satisfy the data requirement.
- <sup>13</sup> **875.1100, 875.1300, 875.1600** - Irvita, through its affiliation with Makhteshim Agan of North America is a member in good standing with the Agricultural Handler's Exposure Task Force (AHETF). AHETF, and the data available through PHED, satisfy these data requirements.
- <sup>14</sup> **875.2200, 875.2400, 875.2500** - Irvita, through its affiliation with Makhteshim Agan of North America is a member in good standing with the Outdoor Residential Exposure Task Force (ORETF) and Agricultural Re-Entry Task Force (ARTF). ORETF and ARTF have submitted data to satisfy these data requirements.
- <sup>15</sup> **835.2370** - This data requirement was waived as per the Oct. 21, 2009 Preliminary Problem Formulation.

## Endnotes for Data Matrix for Azoxystrobin Technical NC

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<sup>16</sup> **835.4400** – These data were not required as per the Oct. 21, 2009 Preliminary Problem Formulation, but EPA did request these data as a part of the registration review process, noting on page 11 of the Problem Formulation that "based on the increased number of uses, EFED is now recommending that the registrant submit an aerobic aquatic metabolism study." Irvita is only proposing to register azoxystrobin on nonfood uses. Nonfood uses would not fall into EFED's reference of "increased number of uses", therefore, aerobic aquatic metabolism data are not required for Irvita's azoxystrobin proposed registration.

<sup>17</sup> **835.1410** – This data requirement was waived as per the Oct. 21, 2009 Preliminary Problem Formulation.

<sup>18</sup> **835.8100** – This data requirement was waived as per the Oct. 21, 2009 Preliminary Problem Formulation.

<sup>19</sup> **835.6100** – The studies cited are considered acceptable and satisfy the data requirement as per the Oct. 21, 2009 Preliminary Problem Formulation.

<sup>20</sup> **835.6200** – These data were not required as per the Oct. 21, 2009 Preliminary Problem Formulation.

<sup>21</sup> **835.6300** – These data were not required as per the Oct. 21, 2009 Preliminary Problem Formulation.

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## DATA MATRIX

Date: April 9, 2013		EPA Reg. No./File Symbol: 74054 -xxx		Page 1 of 10	
Applicant's/Registrant's Name & Address: Ivita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604		Product:  Azoxystrobin Technical NC			
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Specific Data Requirements</b>					
			Ivita Plant Protection N.V.	OWN	
			Ivita Plant Protection N.V.	OWN	
			Ivita Plant Protection N.V.	OWN	
					Not Required <sup>1</sup>
			Ivita Plant Protection N.V.	OWN	
			Ivita Plant Protection N.V.	OWN	
			Ivita Plant Protection N.V.	OWN	
			Ivita Plant Protection N.V.	OWN	
			Ivita Plant Protection N.V.	OWN	
			Ivita Plant Protection N.V.	OWN	
			Ivita Plant Protection N.V.	OWN	
			Ivita Plant Protection N.V.	OWN	
			Ivita Plant Protection N.V.	OWN	

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## DATA MATRIX

Date: April 9, 2013		EPA Reg. No./File Symbol: 74054 -xxx		Page 2 of 10	
Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604		Product: Azoxystrobin Technical NC			
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]				Not Required <sup>2</sup>
[REDACTED]	[REDACTED]				Not Required <sup>2</sup>
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]				Not Required <sup>2</sup>
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]				Not Required <sup>2</sup>
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]				Not Required <sup>2</sup>
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]				Not Required <sup>3</sup>
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]				Not Required <sup>2</sup>
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	

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## DATA MATRIX

Date: April 9, 2013		EPA Reg. No./File Symbol: 74054 -xxx		Page 3 of 10	
Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604		Product:  Azoxystrobin Technical NC			
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]				See 830.7550
[REDACTED]	[REDACTED]				See 830.7550
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]				See 830.7840
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]				
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]		Irvita Plant Protection N.V.	OWN	
[REDACTED]	[REDACTED]				
[REDACTED]	[REDACTED]				
[REDACTED]	[REDACTED]			PAY	

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## DATA MATRIX

Date: April 9, 2013	EPA Reg. No./File Symbol: 74054 -xxx	Page 4 of 10
Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604		Product:  Azoxystrobin Technical NC

Ingredient: Azoxystrobin (CAS No. 131860-33-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]				Not required <sup>4</sup>
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		OLD	See Endnote <sup>5</sup>
		[REDACTED]		OLD	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]				Not Required <sup>6</sup>
[REDACTED]	[REDACTED]				Not Required <sup>7</sup>
[REDACTED]	[REDACTED]				Not Required <sup>6</sup>

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Date: April 9, 2013

EPA Reg. No./File Symbol: 74054 -xxx

Page 5 of 10

Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V.  
c/o Makhteshim Agan of North America Inc.  
3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

Product:

Azoxystrobin Technical NC

Ingredient: Azoxystrobin (CAS No. 131860-33-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]				Waived <sup>8</sup>
[REDACTED]	[REDACTED]				Not Required
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]				Waived <sup>9</sup>
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]				Not Required

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Date: April 9, 2013

EPA Reg. No./File Symbol: 74054 -xxx

Page 6 of 10

Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V.  
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3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

Product:

Azoxystrobin Technical NC

Ingredient: Azoxystrobin (CAS No. 131860-33-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
██████	████████████████████	██████		PAY	
██████	██████████	██████		PAY	
██████	██████████	██████		PAY	
██████	████████████████████	██████		OLD	See Endnote <sup>10</sup>
		██████		OLD	
		██████		OLD	
██████	██████████	██████		OLD	See Endnote <sup>11</sup>
		██████		OLD	
██████	██████████	██████		OLD	See Endnote <sup>12</sup>
		██████		OLD	
		██████		OLD	
		██████		OLD	
		██████		OLD	
██████	██████████		PHED/AHETF	OWN	See Endnote <sup>13</sup>
██████	██████████				Not Required
██████	██████████		PHED/AHETF	OWN	See Endnote <sup>13</sup>



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## DATA MATRIX

Date: April 9, 2013	EPA Reg. No./File Symbol: 74054 -xxx	Page 7 of 10
Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604	Product: Azoxystrobin Technical NC	

Ingredient: Azoxystrobin (CAS No. 131860-33-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]				Not Required
[REDACTED]	[REDACTED]				Not Required
[REDACTED]	[REDACTED]		PHED/AHETF	OWN	See Endnote <sup>13</sup>
[REDACTED]	[REDACTED]				See Label
[REDACTED]	[REDACTED]				
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]		ARTF/ORETF	OWN	See Endnote <sup>14</sup>
[REDACTED]	[REDACTED]				Not Required
[REDACTED]	[REDACTED]				See Endnote <sup>14</sup>
[REDACTED]	[REDACTED]				See Endnote <sup>14</sup>
[REDACTED]	[REDACTED]				
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]				Not required
[REDACTED]	[REDACTED]				
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]	[REDACTED]		PAY	
[REDACTED]	[REDACTED]				Waived <sup>15</sup>

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## DATA MATRIX

Date: April 9, 2013	EPA Reg. No./File Symbol: 74054 -12	Page 8 of 10
Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604		Product:  Azoxystrobin Technical NC

Ingredient: Azoxystrobin (CAS No. 131860-33-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
██████	████████████████████	██████		PAY	
██████	████████████████████	██████		PAY	
██████	████████████████████	██████		PAY	
██████	████████████████████				Not Required <sup>16</sup>
██████████	████████████████████	██████		PAY	
██████	████████████████████				Waived <sup>17</sup>
██████	████████████████████				Waived <sup>18</sup>
██████	████████████████████	██████ ██████ ██████ ██████ ██████ ██████ ██████ ██████ ██████ ██████		OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD	See Endnote <sup>19</sup>
██████	████████████████████				Not Required <sup>20</sup>
██████	████████████████████				Not Required <sup>21</sup>

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Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860 series	Residue Chemistry Data requirements				Not required
			Syngenta Crop Protection	PAY	
			Gustafson LLC	PAY	
			Loveland Products, Inc.	PAY	
			Tessenderlo Kerley, Inc.	PAY	
			Makhteshim Agan of North America, Inc.	PAY	
			Spray Drift Task Force	OWN	
			Outdoor Residential Exposure Task Force	OWN	
			Agricultural Re-Entry Exposure Task Force	OWN	

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## DATA MATRIX

Date: April 9, 2013		EPA Reg. No./File Symbol: 74054 -xxx		Page 10 of 10	
Applicant's/Registrant's Name & Address: Irvita Plant Protection N.V. c/o Makhteshim Agan of North America Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604		Product: Azoxystrobin Technical NC			
Ingredient: Azoxystrobin (CAS No. 131860-33-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	[REDACTED]		FIFRA Endangered Species Task Force, LLC	PAY	
	[REDACTED]		Agricultural Handlers Exposure Task Force	OWN	
Signature 			Name and Title: Bert Volger, Ph.D. Agent for Irvita Plant Protection N.V.		Date: 4/9/2013

# AZOXYSTROBIN TECHNICAL NC

FUNGICIDE FOR MANUFACTURING USE ONLY

**ACTIVE INGREDIENT:****% BY WT**

Azoxystrobin: methyl(*E*)-2-(2-[6-(2-cyanophenoxy)pyrimidin-4-yloxyphenyl]-3-methoxyacrylate\* .....

96.0%

**OTHER INGREDIENTS:** .....

4.0%

**TOTAL** 100.0%

\*IUPAC

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

**Manufactured for:**

Irvita Plant Protection N.V.  
c/o Makhteshim Agan of North America, Inc.  
3120 Highwoods Blvd., Suite 100  
Raleigh, NC 27604

EPA Reg. No. 74054-xx

EPA Est. No. XXXXXXXXXX

NET CONTENTS: \_\_\_\_\_ Pounds (Kilos)

### FIRST AID

**IF ON SKIN OR CLOTHING:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15 to 20 minutes.
- Call a poison control center or doctor for treatment advice.

**IF INHALED:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance; then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

**IF IN EYES:**

- Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.
- Remove contact lenses, if present, after the first 5 minutes; then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

**Have the product container or label with you when calling a poison control center or doctor or going for treatment.**

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION.** Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

The active ingredient, azoxystrobin, in this product can be persistent for several months or longer. Azoxystrobin has degradation products which have properties similar to chemicals which are known to leach through soil to groundwater under certain conditions as a result of labeled use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

This pesticide is toxic to freshwater and estuarine/marine fish and aquatic invertebrates. Keep out of lakes, streams, ponds, tidal marshes, or estuaries. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Notify state and/or federal authorities immediately if you observe any adverse environmental effects due to the use of this product.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated product which may be labeled for use patterns as listed on this label.

**For Manufacturing Use Only into a Fungicide for the Following Uses:**

1. Terrestrial Nonfood: Uses on golf courses, lawns, and landscape areas around residential, institutional, public, commercial, and industrial buildings, parks, recreational areas, and athletic fields; uses on ornamentals grown in container, bench, flat, plug, bed, or in the field, in greenhouses, shade houses, outdoor nurseries, retail nurseries, and other landscape areas; and
2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
3. Uses for experimental purposes that are in compliance with USEPA requirements.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, cover spill with moist sand, soil, or sawdust. Transfer to a container for disposal. Wash the spillage area with water. Washings must be prevented from entering surface water drains.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Open dumping is prohibited. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

**CONTAINER HANDLING: Nonrefillable Container (flexible-bag-all weights):** Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

### LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

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EPA Reg. No. 74054-xx

EPA Est. No. XXXXXXXXXX

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